

Notice of Allowability

Application No.

09/865,807

Examiner

Monika B Sheinberg

Applicant(s)

CARRINO ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 6/10/2003.
2. ☒ The allowed claim(s) is/are 60,78-119,133,136-141,160-168,176-197 and 204-210.
3. ☒ The drawings filed on 5/25/2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. _____ |
| 5 <input type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____ | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other _____ |

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Michael Davidson on September 19, 2003.

Amendments to Claims 133, 136, 160, 176, 204:

Claim 133 (twice amended). A method for the amplification of at least one target nucleic acid sequence of interest from at least one sample, using an electronically addressable microchip, comprising, for each target nucleic acid sequence of interest:

- a) contacting upstream and downstream oligonucleotide ligation probes with the target nucleic acid sequence such that the 3' terminus of the upstream probe is juxtaposed to the 5' terminus of the downstream probe while both the upstream and downstream probes are in contact with the target nucleic acid sequence;
- b) ligating together the upstream and downstream probes at their respective juxtaposed termini to form a ligated target probe template; and
- c) using the ligated target probe template in a strand displacement amplification ("SDA") reaction to form amplicons of the ligated target probe template, wherein the strand displacement reaction utilizes at least a first SDA primer, each SDA primer comprising a restriction endonuclease sequence on the 5' region of the primer, and no bumper primers are used in the strand displacement amplification,

wherein at least one nucleic acid selected from group consisting of target sequences, ligated target probe templates, and amplicons is electronically addressed in a step (d) to any of a plurality of capture site on the **bioelectronic** microchip.

Claim 136 (twice amended). A method for the amplification of at least one target nucleic acid sequence of interest from at least one sample, using an electronically addressable microchip, comprising, for each target nucleic acid sequence of interest:

a) contacting upstream and downstream oligonucleotide ligation probes with the target nucleic acid sequence such that the 3' terminus of the upstream probe is juxtaposed to the 5' terminus of the downstream probe while both the upstream and downstream probes are in contact with the target nucleic acid sequence;

b) ligating together the upstream and downstream probes at their respective juxtaposed termini to form a ligated target probe template; and

c) using the ligated target probe template in a strand displacement amplification ("SDA") reaction to form amplicons of the ligated target probe template, wherein the strand displacement reaction utilizes at least a first SDA primer and a second SDA primer, the first and second SDA primers being different primers, each SDA primer comprising a restriction endonuclease sequence on the 5' region of the primer, and the first and second SDA primers are contained within a branched primer structure, having the capacity to support strand displacement amplification, and the branched primer is attached to a capture site,

wherein at least one nucleic acid selected from group consisting of target sequences, ligated target probe templates, and amplicons is electronically addressed in a step (d) to any of a plurality of capture site on the **bioelectronic** microchip.

Claim 160 (amended twice). A method for the amplification of at least one target nucleic acid sequence of interest from at least one sample, using an electronically addressable microchip, comprising, for each target nucleic acid sequence of interest:

a) contacting upstream and downstream oligonucleotide ligation probes with the target nucleic acid sequence such that the 3' terminus of the upstream probe is juxtaposed to the 5'

terminus of the downstream probe while both the upstream and downstream probes are in contact with the target nucleic acid sequence;

b) ligating together the upstream and downstream probes at their respective juxtaposed termini to form a ligated target probe template; and

c) using the ligated target probe template in a strand displacement amplification (“SDA”) reaction to form amplicons of the ligated target probe template, wherein the strand displacement reaction utilizes at least a first SDA primer, each SDA primer comprising a restriction endonuclease sequence on the 5’ region of the primer,

wherein least one nucleic acid selected from group consisting of target sequences, ligated target probe templates, and amplicons is electronically addressed in a step (d) to any of a plurality of capture site on the ~~bioelectronic~~ microchip and the upstream and downstream oligonucleotide ligation probes are initially incapable of being ligated together, the method further comprising rendering capable of being ligated together the upstream and downstream oligonucleotide ligation probes prior to ligating the probes together in step (b).

Claim 176 (twice amended). A method for the amplification of at least one target nucleic acid sequence of interest from at least one sample, using an electronically addressable microchip, comprising, for each target nucleic acid sequence of interest:

a) contacting upstream and downstream oligonucleotide ligation probes with the target nucleic acid sequence such that the 3’ terminus of the upstream probe is juxtaposed to the 5’ terminus of the downstream probe while both the upstream and downstream probes are in contact with the target nucleic acid sequence;

b) ligating together the upstream and downstream probes at their respective juxtaposed termini to form a ligated target probe template; and

c) using the ligated target probe template in a strand displacement amplification (“SDA”) reaction to form amplicons of the ligated target probe template, wherein the strand displacement reaction utilizes at least a first SDA primer and a second SDA primer, the first and second SDA primers being different primers, each SDA primer comprising a restriction endonuclease sequence on the 5’ region of the primer, and the strand displacement amplification utilizes an unequal concentration ration of the first SDA primer to the second SDA primer,

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wherein the first and second SDA primers are different primers and form a set of primers, and wherein unequal populations of complementary first and second amplified strands of the target nucleic acids are formed,

wherein at least one nucleic acid selected from group consisting of target sequences, ligated target probe templates, and amplicons is electronically addressed in a step (d) to any of a plurality of capture site on the **bioelectronic** microchip.

Claim 204 (twice amended). A method for the amplification of at least one target nucleic acid sequence of interest from at least one sample, using an electronically addressable microchip, comprising, for each target nucleic acid sequence of interest:

a) contacting upstream and downstream oligonucleotide ligation probes with the target nucleic acid sequence such that the 3' terminus of the upstream probe is juxtaposed to the 5' terminus of the downstream probe while both the upstream and downstream probes are in contact with the target nucleic acid sequence;

b) ligating together the upstream and downstream probes at their respective juxtaposed termini to form a ligated target probe template; and

c) using the ligated target probe template in a strand displacement amplification ("SDA") reaction to form amplicons of the ligated target probe template, wherein the strand displacement reaction utilizes at least a first SDA primer, each SDA primer comprising a restriction endonuclease sequence on the 5' region of the primer,

wherein at least one nucleic acid selected from group consisting of target sequences, ligated target probe templates, and amplicons is electronically addressed in a step (d) to any of a plurality of capture site on the **bioelectronic** microchip,

wherein allele specific strand displacement amplification is carried out for target nucleic acids of interest which encode a gene with two or more known alleles,

wherein the upstream and downstream ligation probe sequences are selected to be specific for a particular allele of the gene, so that the ligation probes contact, proximate the 3' end of the upstream probe or proximate the 5' end of the downstream probe, a nucleotide sequence of the target nucleic acid sequence which determinative of the particular allele,

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wherein, if the target nucleic acid does not contain the sequence determinative of the allele for which the ligation probes are selected, the juxtaposed terminus of one of the probes is misaligned, so that, in step (b), the ligation probes are ligated only if the target nucleic acid sequence contains the allele determinative sequence, and

wherein, in step c), amplicons are produced by strand displacement amplification of the allele determinative sequence is contained within the target nucleic acid sequence.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 9 A.M to 5 P.M. If attempts to reach the examiner by telephone are unsuccessful, the primary examiner in charge of the prosecution of this case, Carla Myers, can be reached at 703-308-2199. If attempts to reach the examiners are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Chantae Dessau, whose telephone number is (703) 605-1237, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

September 22, 2003
Monika B. Sheinberg
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MB

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER